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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,021	12/21/2001	Yasumichi Hitoshi	021044-001210US	6123

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EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	
MAIL DATE	**DELIVERY MODE**
05/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/026,021	HITOSHI ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,10,24,25,32,33 and 36-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,10,24,25,32,33 and 36-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 27, 2007 has been entered. Applicant has not submitted listing of claims with the RCE. The allowance notice mailed on 11-30-2006 stated claims 9, 10, 24, 25, 32, 33, and 36-38 are allowed, and all other claims were cancelled. Therefore, this Office action is based on the status of claims at the time of allowance on 11-30-2006.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 9, 10, 24, 25, 32, 33, and 36-38 are pending and examined on merits.

Claim Rejections - 35 USC § 103

Claims 9, 10, 24, 25, 32, 33, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,650,501 A of record in WO 01/53312 (Tang) A1 of record.

Claims 9, 10, 24, 25, 32, 33, 36, and 37 are drawn to method of identifying a compound that modulates cellular proliferation by measuring kinase activity of SAK polypeptide when said compound is contacted with a SAK polypeptide encoded by a nucleic acid encoding a SAK polypeptide having at least 95% sequence identity to

instant SEQ ID NO:2 protein, wherein the kinase is measured in vitro (claim 10), the modulation is inhibition of cellular proliferation (claim 24), the polypeptide being recombinant (claim 32), wherein the compound is an antibody (claim 34), wherein the polypeptide in the base claim is encoded by **a** sequence of SEQ ID NO: 1, or a small organic molecule (claim 36), or a peptide (claim 37).

The '501 patent teaches method of identifying a compound that modulates cellular proliferation by measuring kinase activity of SAK polypeptide when said compound is contacted with a SAK polypeptide encoded by a nucleic acid encoding a SAK polypeptide having at least 77% sequence identity to instant SEQ ID NO:2 protein. In addition, the '501 patent teach kinase measurement in vitro, the modulation is inhibition of cellular proliferation the polypeptide being recombinant wherein the compound is an antibody or a small organic molecule (antisense), or a peptide. Note column 4 lines 41-45, the paragraph bridging columns 4 and 5, column 18 lines 27-57. Claim 33 is included in this rejection because the term "nucleic acid comprising a sequence of SEQ ID NO: 1" is interpreted as any nucleic acid comprising a fragment of SEQ ID NO: 1. Amending the limitation to "nucleic acid comprising the sequence of SEQ ID NO: 1" or "nucleic acid comprising SEQ ID NO: 1" would make the scope of the claimed polypeptide being used in the method to be the polypeptide encoded by SEQ ID NO: 1.

The difference between the instantly claimed method and the method of the '501 patent is that the instant method uses SAK polypeptide having at least 95% sequence identity to instant SEQ ID NO: 2 protein, while the SAK polypeptide disclosed in '501

patent is SAK polypeptide having at least 77% sequence identity to instant SEQ ID NO: 2 protein. Note the previously provided sequence alignment.

However, WO 01/53312 A1 teaches a SAK polypeptide that is 99.9% identical (i.e. SEQ ID NO: 2389) to the instant SEQ ID NO: 2 (see previously provided Exhibit B) encoded by a recombinant nucleic acid (i.e. SEQ ID NO: 603) that is 99.9 % identical to instant SEQ ID NO: 1 (see previously provided Exhibit C, and pages 89-91.

The main point of this rejection is that the '501 patent at column 1 under the heading Background of Invention teaches that 47% sequence identity to the catalytic domain of a kinase polypeptide would be enough that the protein in question would a kinase. This teaching suggests that one of ordinary skill in the serine/threonine kinase art would recognize the SAK polypeptide of Tang, which has at least 77% sequence identity to the SAK kinase of the '501, would have kinase activity.

Therefore, it would have been obvious for one of ordinary skill to arrive at the claimed invention with a reasonable expectation of success, because the '510 patent teaches an assay to identify a compound for modulating proliferation, especially to treat the various cancers, by determining the kinase activity of a SAK polypeptide, and Tang teaches a SAK polypeptide 99.9% identical (i.e. SEQ ID NO: 2389) to the instant SEQ ID NO:2. One of ordinary skill would have been motivated to make and use the claimed invention to isolate a proliferation-modulating compound for cancer treatment.

Claims 9, 37, and **38** are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,650,501 A of record (22 July 1997) in view of WO 01/53312 A1 of record

(Tang) in view of and further in view of US 5,589,356 A (31 December 1996, the '356 patent from now on).

Claims 9, 37, and 38 are interpreted as drawn to method of identifying a useful circular peptide by determining whether or not said circular peptide affecting cellular proliferation when said compound is contacted with a SAK polypeptide.

See above what the '501 patent and Tang teach. Neither the '501 patent nor Tang teaches circular peptide.

However, the '356 patent teaches (at the front page) a circular peptide and also teach that a usefulness of a circular peptide as a therapeutic has been recognized in the art before the effective filing date of the instant application (note column 3, lines 3-4).

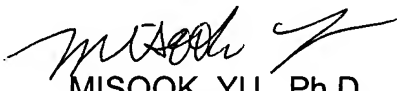
Therefore, it would have been obvious to one of ordinary skill in the art to add a circular peptide to see whether the circular peptide modulates cellular proliferation, given that the '501 patent teaches that a SAK protein is involved in cellular proliferation, and WO 01/53312 A1 teaches a SAK polypeptide that meets the claimed limitation and the '356 patent teaches many circular peptides. One of ordinary skill in the art would have been able to accomplish the claimed method with a reasonable expectation of success, because WO 01/53312 A1 teaches a SAK polypeptide that meets the amended limitation. One of ordinary skill would have been motivated to screen a circular peptide with the art-known detection methods as described by the '501 paten, given that the '356 patent teaches that a circular peptide might be a candidate therapeutic.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MISOOK YU, Ph.D.
Primary Examiner
Art Unit 1642